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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,637	01/07/2005	Etienne Robert Alfred Grasset	468.001	9534
47888 7590 02/26/2009 HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
EXAMINER				
BADJO, BARBARA P				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
02/26/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/520,637

**Applicant(s)**

GRASSET ET AL.

**Examiner**

Barbara P. Badio

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7-14 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 7-13 and 34-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_

**Nonfinal Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Election/Restrictions***

2. The examiner notes the error in the recitation of the claims under examination in the previous Office Action. Claim 6 (now cancelled) was erroneously included in the claims under examination.

3. Claims 1-4, 7-14 and 34-42 are pending in the present application. Based on applicant's election of 3,5-dienes, claims 1-4, 7-13 and 34-42 stand withdrawn from further consideration as being drawn to a nonelected invention. Claim 7 will be examined to the extent it reads on 3,5-dienes derivatives.

Note: It is noted that the specific steroids recited by instant claim 1 are not inclusive of 3,5-dienes.

***Claim Rejections - 35 USC § 112***

4. The rejection of claim 5 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is made moot by the cancellation of the instant claim.

**5. The rejection of claims 1-4, 7-9 and 34-42 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is withdrawn.**

The withdrawn is based on the exclusion of the elected 3,5-dienes from the instant claims as currently amended.

**6. The rejection of claims 34 and 35 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.**

The withdrawn is based on the exclusion of the elected 3,5-dienes from the instant claims as currently amended.

**Response to Applicant's Argument**

Applicant argues risk factors that influence preterm births and the fact that said clinical symptoms may be monitored and used to determine women having a risk of preterm birth. According to applicant, in these conditions, this treatment is not a preventive treatment, it is treatment for women at risk. Applicant's argument was considered but not persuasive for the following reason.

The instant claims are drawn to a composition or method of **preventing** premature births. As noted in the previous Office Action, prevention implies administration of the claimed compound/composition result in the cessation of the condition/disease. However, the instant specification lacks evidence that administration of the claimed compound/composition would result in the prevention of premature

births. Treatment of women at risk of premature birth is not equivalent to preventing said in these woman without supporting evidence.

7. The rejection of claims 5 and 6 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.

8. The rejection of claims 1-4, 7-9, 12-14 and 34-42 under 35 USC 112, second paragraph is withdrawn.

*Claim Rejections - 35 USC § 102*

9. The rejection of claim 5 under 35 USC 102(b) over Hodosan et al. (Arzneimittel-Forschung, 1969) is made moot by the cancellation of the instant claim.

10. The rejection of claims 1-4, 7 and 8 under 35 USC 102(b) over Hodosan et al. (Arzneimittel-Forschung, 1969) is withdrawn.

*Claim Rejections - 35 USC § 103*

11. The rejection of claim 34 under 35 USC 103(a) over Hodosan et al. (Arzneimittel-Forschung, 1969) is withdrawn.

***Conclusion***

12. This application is in condition for allowance except for the following formal matters:

Claim 14 is allowable to the extent it read on 3,5-dienes. The instant claim is objected to (a) as being dependent on a withdrawn claim and (b) as reciting a nonelected invention.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

***Telephone Inquiry***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/  
Primary Examiner, Art Unit 1612